K021923

JUN 17 2002

7.

510(K) SUMMARY

21CFR 807.92

INTRODUCTION

This 510(K) Premarket Notification has been prepared to demonstrate that the CardioSPECT SC and CardioSPECT D90 Gamma ECT, manufactured by NC Systems, Inc. is substantially equivalent to the NC Systems, Inc. QUAD which has previously under went the 510(K) premarket notification process and approved (K013353).

1. SUBMITTER IDENTIFICATION

Applicant's Name and Street Address: Nuclear Cardiology Systems, Inc.
dba NC Systems, Inc.
5660 Airport Blvd., Suite 101
Boulder, Colorado 80301

Contact Person: Charles H. Rose

Telephone and Fax Numbers of Contact Person: T-(303) 541-0044
800-548-4024
F-(303) 541-0066

Address of Manufacturing Site: Alsotorokvesz 14
H-1022 Budapest, Hungary

Date of Submission: February 4, 2002

2. DEVICE NAME

Device Name (common):	Gamma Camera-SPECT Gamma Camera
Proprietary Name:	CardioSPECT SC and CardioSPECT D90
Classification Name: (ECT)	Emission Computed Tomography System

Regulatory Class:	II
Product Code:	90KPS
Regulation Number:	21CFR 892.1200
Classification Panel	Radiological

3. IDENTIFICATION OF EQUIVALENT DEVICE

The equivalent device is the:

Re: K013353
Trade/Device Name: NeuroSpect QUAD ECT System
Regulation Number: 21CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS

This device, the QUAD, is also manufactured by the applicant, NC Systems, Inc. and has the same technology characteristics as the applicant device.

The equivalent device, the QUAD, is a scintillation detector, NaI, system with PMT light gathering capacity. The system configuration is a four (4) detector system with the mechanical ability to rotate the detectors around the patient. The system uses a collimator on each detector to permit spatial image resolution of the gamma photons emitted from the patient. The collimators lock in place. There is no built-in radioactive scanning source and none is required. The QUAD is capable of both Planar (Class I) and SPECT (ECT) (Class II) operation. The acquisition/processing computer is a presently approved system sold and supported by NC Systems, Inc. but manufactured by the Segami Corporation.

4. DEVICES SUBJECT TO PRE-MARKET NOTIFICATION (APPLICANT DEVICE)

The applicant device subject to this pre-market notification submission are the SC and D90 ECT systems which are submitted under a single application as they are equivalent devices with substantially equivalent specifications, safety and intended use.

a) The SC and D90 are scintillation detector, NaI, systems with PMT light gathering capacity. The D90 has two (2) detectors and the SC has one detector both with the ability to rotate these detectors around the patient. The system uses a collimator on each detector to permit spatial image resolution of the gamma photons emitted from the patient. The collimators lock in place. There is no built-in radioactive scanning source and none is required. The SC and D90 are capable of both Planar (Class I) and SPECT or ECT (Class ii) operation. The acquisition/processing computer is a presently approved system sold and supported by NC Systems, Inc. but manufactured by Segami Corporation. This application is for the ECT device-gamma camera-system(s) and not the previously approved computer.

b) The electrical and mechanical components as well as the manufacturing specifications of the applicant systems, the SC and D90 are substantially equivalent to the QUAD, the legally marketed device.

c) Specifications: Are provided in Attachment 2.

5. INTENDED USE

The intended use of the CardioSPECT SC and the CardioSPECT D90 is to detect the location and distribution of gamma ray emitting radionuclides in the human body and store the data for analysis as the same equivalent device, K013353.

6. DETERMINE OF SUBSTANTIAL EQUIVALENCE

The SC and D90 systems have been compared to the legally marketed QUAD system and determined to be substantially equivalent.

a) The specifications are compared on Enclosure G.a.

b) The Hazard Analysis is compared on Enclosure 6.b pgs 1-2.
c) The labeling, technology, engineering, performance and materials are compared on Enclosure 6.c.

d) References to Mediso have been previously addressed as referring to the manufacturing of NC Systems.

e) The non-clinical tests submitted were performed on the applicant systems, the SC and D90 in the same manner as the pre-approved QUAD system. These tests were performed under the same standards as the pre-approved QUAD systems.

f) The clinical tests submitted were performed on, and clearly identified, the SC and D(). The subjects were adults who were under the care of a physician licensed to perform these procedures. These procedures were performed as requested for the application.

g) The conclusion of the non-clinical and clinical tests demonstrate that the device (SC & D90) is safe, as effective and performs well or better than the legally marketed device identified in paragraph 3.(a) of this section.

h) The differences between the legally marketed system QUAD and the applicant systems SC and D() are in the number of detectors used for data acquisition. The change in the number of detectors:

QUAD 4
SC 1
D90 2

permit changes in the area imaged and the image acquisition time. These changes do not alter the safety and effectiveness of the systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2002

Nuclear Cardiology Systems, Inc.
% Mr. Wolfram Gmelin
Technical Manager, Third Party Review
TÜV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K021823
Trade/Device Name: CardioSPECT SC and CardioSPECT D90
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: 90 KPS
Dated: May 30, 2002
Received: June 4, 2002

Dear Mr. Gmelin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

U.S. Food and Drug Administration - Center for Devices and Radiological Health

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510(k) Number (if known): K021823

Device Name: CARDIOSPECT SC AND CARDIOSPECT D 90

Indications for Use:

Intended use is to detect & image the distribution of radionuclides in the body, when the radiopharmaceutical is administered in the body.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE) [signature]

prescription use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021823